REMARKS

Upon entry of the present Amendment, claims 1-23, 25-34, 56, 57, 67, 68, 92-95 and 115 will be pending. Claims 24, 35-55, 58-66, 69-91 and 96-114 are withdrawn from consideration and/or canceled. Applicants reserve the rights to pursue the withdrawn and/or canceled subject matter in a subsequent application. Support for amended claim 1 for reciting "a binding partner that is capable of binding to a moiety to be manipulated" can be found throughout the application and, *inter alia*, in the original claim 24. Claims 5, 22, 25-27, 32 and 57 are amended to conform with the amendment of claim 1 and/or for formality reasons. Support for new claim 115 for reciting a microdevice "which does not comprise a microprocessor" can be found throughout the application and, *inter alia*, in the exemplary microdevices shown in Figures 1-12 of the present application. The Abstract is amended for formality reasons as well. The above-described amendments do not introduce any new matter into the present application.

Specification

The Examiner stated that the language should be clear and concise and should not repeat information given in the title. The Examiner also stated that it should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc. The Examiner further stated that Applicant is reminded that legal phraseology should be avoided in the abstract, i.e. line 4, "coding pattern on said substrate." The Examiner requested that appropriate correction is required.

The Abstract is amended to address the Examiner's concern on the use of "said" in the Abstract. If the Examiner believes that the amendment does not address all of the Examiner's

concerns on the Abstract, Applicants welcomes the Examiner's specific suggestion(s) as to how the current Abstract should be amended.

Rejections under 35 U.S.C. § 112

Claims 5, 10, 22, 26 and 57 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 5, line 4, "other regular or irregular shape" is allegedly vague and indefinite. It is unclear allegedly how applicants define "regular" and "irregular" shape of the substance. With respect to claim 5, line 4, "other regular or irregular shape" is allegedly vague and indefinite. The usage of "or" is allegedly inconsistent with the Markaush group claim language.

This rejection is rendered moot by the amendment of claim 5.

With respect to claim 10, "wherein the substrate is in an irregular shape," is allegedly vague and indefinite. It is allegedly unclear what applicants refer to an "irregular" shape.

This rejection is respectfully traversed. Definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of prior art, and (3) the interpretation claims would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. Claims need only "reasonably apprise those skilled in the art" of their scope and be "as precise as the subject permits." Hybritech Inc. v. Monoclonal Antibodies, Inc., 231 USPQ 81, 94 (Fed. Cir. 1986), cert. den., 480 U.S. 947 (1987). The Court in Orthokinetics, Inc v. Safety Travel Chairs, Inc., 1 USPQ2d 1081 (Fed. Cir. 1986) held that a claim limitation requiring that a pediatric wheelchair

part be "so dimensioned as to be insertable through the space between the doorframe of an automobile and one of the seats" is definite. The Court stated:

The phrase 'so dimensioned' is as accurate as the subject matter permits, automobiles being of various sizes. As long as those of ordinary skill in the art realized that the dimensions could be easily obtained, § 112, 2d ¶ requires nothing more. The patent law does not require that all possible lengths corresponding to the spaces in hundreds of different automobiles be listed in the patent, let alone that they be listed in the claims.

1 USPQ2d at 1088. What constitutes a "regular shape" is well known in the art and exemplary "regular shapes" are disclosed in the present specification such as sphere, square, rectangle, triangle, circular disc, cube-like shape, cube, rectangular parallelepiped (cuboid), cone, cylinder, prism, pyramid, and right-angled circular cylinder, etc. An "irregular shape" is simply the opposite to a "regular shape." Claim 10 is indented to cover all possible irregular shapes and Applicants should not be required to list all possible irregular shapes. In addition, an "irregular shape" can also be viewed as a negative limitation and the "current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation." MPEP 2173.05(i). "So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of 35 U.S.C. § 112, second paragraph." *Id.*

With respect to claim 10, "having a single-dimension from about 1 micron to about 50 microns," is allegedly vague and indefinite. It is allegedly unclear what "single-dimension" applicants refer to.

This rejection is rendered moot by the amendment of claim 10.

With respect to claim 22, "wherein the substance is comprised within the substrate," is allegedly vague and confusing. It is allegedly unclear what "comprised" applicants refer to. The

Examiner inquired whether it means that the substance is evenly distributed within the substrate?

The Examiner reminded Applicants that the wording "comprised" in claim language has special legal meaning and requested appropriate correction.

This rejection is rendered moot by the amendment of claim 22 wherein "comprised" is replaced with "contained." As to the Examiner's question whether it means that the substance is evenly distributed within the substrate, Applicants point out that claim 22 covers a device wherein the substance is "contained" within the substrate, whether or not the substance is evenly or unevenly "contained" within the substrate.

With respect to claim 26, line 2, "a molecule and an aggregate or complex thereof," is allegedly vague and indefinite. It is unclear allegedly what applicants refer "a molecule and an aggregate or a complex" in this claim context.

This rejection is rendered moot by the amendment of claim 22 wherein what constitutes an aggregate or a complex is clearly spelled out.

With respect to claim 57, "further comprising instruction(s) for coupling the moiety to the microdevice, " is allegedly vague and indefinite. It is allegedly unclear what "instructions" applicants refer as to couple the moiety to the microdevice.

This rejection is rendered moot by the amendment of claim 22 wherein it is made clear that "instruction(s)" means an instruction for coupling the moiety to the microdevice and/or an instruction for manipulating the moiety-microdevice complex on the chip.

It is respectfully submitted that the rejection of claims 5, 10, 22, 26 and 57 under 35 U.S.C. § 112, second paragraph, is overcome by the amendments and must be withdrawn.

Rejections under 35 U.S.C. § 102

Corless

Claims 1-2 are rejected under 35 U.S.C. 102 (b) as being allegedly anticipated by Corless, WO 99/47254 (Corless). Corless is alleged to teach a microdevice having a substrate and photomask coding pattern on the substrate for identification purposes in combinatorial chemistry. The Examiner asserted that Corless' invention does not need anodization of the surface layer. Corless is alleged to teach using different materials for the substrate, *i.e.*, ceramic, glasses, and polymers.

In the interests of advancing prosecution of the present application and without accepting the Examiner's assertion, Applicants have amended claim 1 to incorporate the limitation from original claim 24. As recognized by the Examiner, Corless does not anticipate original claim 24. Accordingly, Corless does not anticipate amended claim 1. Corless does not anticipate claim 2 as claim 2 depends on claim 1.

Drexler

Claims 1, 2, 5, 7, 8, 15-17, and 21-22 and 92-94 are rejected under 35 U.S.C. 102(e) as being allegedly anticipated by Drexler, U.S. Patent No. 6,318,633 (Drexler). Drexler is alleged to teach the following:

- a microdevice for laser writing on smart/optical cards;
- coating a substrate, i.e. plastic or polycarbonate, as memory data for photorecognition of the optical card;
- Drexler's invention does not need of anodization of the metal surface;
- having a diameter of circular disc shape disc between 0.6 to 3.0 micron and the substrate having rectangle surface area around 360 square micron;

- immobilized secondary substrate on the primary base substrate for laser reflectivity recording;
- other sizes or orientation of laser detectable strips could be used;
- Drexler's reference does not comprise a porous surface; and
- various reflective metals such as Bi, Te, Sn, Cu, Al, Pt, Au, Rh, As, Sb, Ge, Se,
 Ga as laser recording material and covering with a protective non-metal surface
 layer, i.e. plastic or polycarbonate where the laser optical recognizable pattern
 formed various holes within the substrate.

In the interests of advancing prosecution of the present application and without accepting the Examiner's assertion, Applicants have amended claim 1 to incorporate the limitation from original claim 24. As recognized by the Examiner, Drexler does not anticipate original claim 24. Accordingly, Drexler does not anticipate amended claim 1. Drexler does not anticipate claims 2, 5, 7, 8, 15-17, and 21-22 and 92-94 as claims 2, 5, 7, 8, 15-17, and 21-22 and 92-94 depend on claim 1. Since this is the only prior art based rejection of claims 92-94, it is respectfully submitted that claims 92-94 are free of prior art once this rejection is overcome.

Rejections under 35 U.S.C. § 103

Drexler and Zhou

Claims 3-4, 6, 9-14, 18-20, 23-34, 56-57, 67-68 are rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Drexler in view of Zhou et al., U.S. Patent No. 6,355,491 (Zhou).

The Examiner acknowledged that Drexler does not explicitly teach detecting biomolecules, or analytes in a tested sample. Zhou et is alleged to teach the following:

- a microarray device using different materials for the substrate, including silicon dioxide or silicon nitride, glass, ceramics or plastics;
- a hydrophilic or hydrophobic molecule coating on the substrate;
- various shapes of the substrate;
- flexible thickness of the substrate from 0.1 to 500 μm;
- photolithographical substrates, sputtering aluminum layer on the silicon layer, or using magnetic material, i.e. ferromagnetic or ferromagnetic materials, nickel metal layer;
- manipulation of binding partner/binding molecules by external forces, i.e. electric current where the binding partners consisting of a cellular organelle, i.e. receptor,
 DNA or RNA molecules;
- using magnetic or conductive and/or insulating materials for manipulation, or applying external physical forces, such as magnetic field;
- using porous or non-porous materials on the surface; and
- various markers and indicators, i.e. fluorescent dye, for detection purposes.

Although the Examiner recognized that Drexler does not explicitly teach detecting biomolecules, the Examiner asserted that Drexler's teaching is nevertheless purported to purposes of authentication, validation or identification of objects with application of photorecognizable laser detection technique. The Examiner also asserted that both Drexler and Zhou are directed to solving the similar type of problem, i.e. identification of objects with photorecognition means, such as laser or fluorescent light. The Examiner further asserted that it would have obvious to one of ordinary skilled in the art at the time the invention was made to have provided the microarray device of Zhou with the photorecognizable laser barcode as taught

by Drexler since allegedly the skilled in the relating microarray detection would have been expected to consider those areas of art which have similar problems, in seeking a solution.

With respect to claims 9-10, Zhou is alleged to teach the claimed invention except for the certain diameter of the side-width of the cube-like shape or the single-dimension of an irregular shape of the substrates. the Examiner asserted it would have been an obvious matter of design choice to modify all the possible shape and size of the instant claims, since such a modification would have been involved a mere change in the size of a component.

This rejection is respectfully traversed. Drexler and Zhou, whether alone or in combination, do not render the presently claimed invention obvious because there is no motivation, whether explicitly or implicitly, to combine the teachings of Drexler and Zhou to arrive at the presently claimed microdevices, kits and arrays.

Applicants respectfully submit that Zhou is not a proper reference under 35 U.S.C. § 103(a) because the instant application and Zhou are subject to an obligation of assignment to the same person. Applicants are assuming that Zhou is being cited as a reference under 35 U.S.C. § 102(e), although the Action did not indicate the subsection of 102 relied upon by the Examiner. Zhou and the instant application were both subject to assignment to Aviva Biosciences Corporation at the time the invention was made and are still owned by Aviva Biosciences Corporation. The assignment of the instant application to Aviva Biosciences Corporation was recorded in the Office on December 4, 2001 on Reel 012338 and Frame 0361. The assignment of Zhou to Aviva Biosciences Corporation was recorded in the Office on September 14, 2000 on Reel 011091 and Frame 0191. Therefore, under 35 U.S.C. § 103(c), Zhou does not qualify as a prior art reference for the presently claimed microdevices, kits and arrays.

Even assuming, *arguendo*, that Zhou was a proper reference, the presently claimed microdevices, kits and arrays are not obvious over Drexler and Zhou for the following reasons.

The nature of the motivation required in order to justify combining documents in support of an art rejection has been outlined by the Federal Circuit in In re Rouffet, 47 USPQ2d 1453 (Fed. Cir. 1998). As there clearly set forth, only three recognized motivations are acceptable. The first is a suggestion in the documents themselves. There is no such suggestion here either in Drexler or Zhou to combine the teachings of the two references. The second possible rationale lies in the nature of the problem to be solved. What problem would this be? The Examiner acknowledged that Drexler's reference does not explicitly teach detecting biomolecules, but alleged that Drexler's teaching is nevertheless purported to purposes of authentication, validation or identification of objects with application of photorecognizable laser detection technique. However, as explicitly stated in Drexler, its smart cards are for authentication, validation, authorization or identification involving Internet and Intranet E-Commerce transactions (See Drexler at column 2, lines 42-48). As such, the smart cards of Drexler are for identification purpose only, and are not used for any manipulation purposes. In contrast, Zhou is directed to electromagnetic chips and arrays and the use of such chips and arrays for manipulating particles. Zhou has nothing to do with Internet and Intranet E-Commerce transactions. Thus Drexler and Zhou are in two distinct fields and there is no common problem to be solved here. The third and final criterion is clearly not present - the notorious nature of at least one document cited such that everyone in the field would be expected to be aware of it.

In fact, Drexler teaches away from such combination to arrive at the presently claimed invention. The test for "teaching away" is that a "reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the

result sought by the applicant." In re Gurley, 27 F.3d 551, 553, 31 USPQ.2D 1130, 1131 (Fed. Cir. 1994). In addition, if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) (Claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were located at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. The Board concluded the claims were prima facie obvious, reasoning that it would have been obvious to turn the reference device upside down. The Court reversed, finding that if the prior art device was turned upside down it would be inoperable for its intended purpose because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged.).

As discussed above, Drexler's smart cards are used for authentication, validation, authorization or identification involving Internet and Intranet E-Commerce transactions. If Drexler were to be combined with Zhou to arrive at the presently claimed invention, a binding partner that is capable of binding to a moiety to be manipulated would be added to Drexler's smart cards. But why would skilled artisans add the binding partner to Drexler's smart cards in view of Zhou? Other than increasing production cost, the addition would not have any benefit for the purpose of Drexler's smart cards, *i.e.*, authentication, validation, authorization or

identification involving Internet and Intranet E-Commerce transactions. In addition, if Drexler were to be combined with Zhou to arrive at the presently claimed microdevice of claim 115, *i.e.*, a microdevice which does not comprise a microprocessor, such a combination would render Drexler's smart cards inoperable for their intended purpose. To be used in Internet and Intranet E-Commerce transactions, Drexler's smart cards must contain a microprocessor (*See* Drexler at column 2, line 56 through column 3, line 5 and all claims). Removing the microprocessor from the Drexler's smart cards, as required by the present claim 115, would totally defeat the purpose of Drexler's smart cards.

Further, combining Drexler and Zhou to arrive at the presently claimed invention is contradictory to the Examiner's own position in the December 3, 2002 Restriction Requirement. In that Restriction Requirement, the Examiner restricted Group I (Claims 1-34, 56-57, 67-68 and 92-95) from Group II (Claims 35-41), Group III (Claims 42-45), Group IV (Claims 58-66) and other claims. In other words, the Examiner took the position that claims of Group I, *i.e.*, the claims under current consideration, are <u>patentably distinct</u> from claims of the other Groups including Groups II-IV. In paragraph 2 of the December 3, 2002 Restriction Requirement, the Examiner stated:

In this case invention I can be used as a <u>materially different method</u> other than the methods claimed by inventions II -V, such as for identification of counterfeit coins with a specific fluorescence other than isolating moieties, manipulating moieties, detecting moieties or array for detecting moieties or synthesizing an entity corresponding to the photrecognizable coding pattern (emphasis added).

Even though microdevices of Group I can be used in the methods for isolating, manipulating and detecting moieties of Group II-IV, the Examiner still regarded Group I as patentably distinct from Groups II-IV. Now, the Examiner is combining Zhou, which is directed to chips and arrays

for manipulating moieties with Drexler, which is directed to smart cards for Internet and Intranet E-Commerce transactions.

Drexler, Zhou and Wang

Claim 95 is rejected under 35 U.S.C. 103 (a) as being allegedly unpatentable over Drexler in view of Zhou as applied to the claims mentioned above, and further in view of Wang et al., *IEEE Transactions on Industry Applications*, 33:660-669 (1997) (Wang).

The Examiner acknowledged that Drexer and Zhou fail to apply an external force that is not magnetic force. Wang is alleged to teach using various physical forces, such as mechanical, hydrodynamic, ultrasonic, optical and dielectrophoretic for application of cellular isolation, separation and characterization. The Examiner alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the microdevice of Drexler with varieties of options on the external forces other than magnetic forces as taught by Zhou, such as ultrasonic or hyrodynamic as taught by Wang, to manipulate and detect the binding of analytes of interest in a sample.

This rejection is respectfully traversed for the same reasons, as discussed above, in connection with the obviousness rejection over Drexler in view of Zhou. Wang, like Zhou, is about using various forces to manipulate particles and has nothing to do with Internet and Intranet E-Commerce transactions. Why would skilled artisans add the binding partner to Drexler's smart cards in view of Zhou and Wang? Other than increasing production cost, the addition would not have any benefit for the purpose of Drexler's smart cards, *i.e.*, authentication, validation, authorization or identification involving Internet and Intranet E-Commerce transactions. In addition, if Drexler were to be combined with Zhou and Wang to arrive at the

presently claimed microdevice of claim 115, *i.e.*, a microdevice which does not comprise a microprocessor, such a combination would render Drexler's smart cards inoperable for their intended purpose.

It is respectfully submitted that the rejections of claims 3-4, 6, 9-14, 18-20, 23-34, 56-57, 67-68 and 95 under 35 U.S.C. § 103 have been overcome by the above remarks and/or amendments and must be withdrawn.

CONCLUSION

Applicants submit that the rejections of claims 1-23, 25-34, 56, 57, 67, 68 and 92-95 under 35 U.S.C. §§ 102, 103 and 112 have been overcome by the above remarks and/or amendments. Early allowance of the pending claims 1-23, 25-34, 56, 57, 67, 68, 92-95 and 115 are earnestly requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. <u>471842000500</u>.

Respectfully submitted,

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